K 123650

510(k) Summary of Safety

FEB 2 0 2013

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

November 1, 2012

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Felipe Cuaranta Monroy, Chief Software Development
COMPAÑÍA MEXICANA DE RADIOLOGÍA CGR, SA de CV.
Fraccionamiento Industrial s/n
El Marqués Querétaro, Querétaro
México, 76240
Email: fcuaranta@cmr3.com.mx
Phone: +52 4422215000 Ext 138

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Product Name:	ARiX RAD Acquisition Console™
Common Name:	Picture, archive and communications system
Classification	Name: System, Image Processing, Radiological
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

ARiX RAD Acquisition Console™ is substantially equivalent to:

	system, image processing, radiological
510(K) Number	K110033
Device Name	FEEL-DRCS
Applicant	IMFOU CO., LTD #821 Samil Plaza, 837-26 Yeuksam-dong Gangnam-gu, Seoul, Korea
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	02/28/2011
Decision Date	09/15/2011
Decision	substantially equivalent (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology
summary	summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

510(k) Summary of Safety

Device Description: 21 CFR 807 92(a)(4)

- The ARiX RAD Acquisition Console™ is software used together with a digital X-ray image acquisition system that uses a digital detector and a Compact GMX RAD X ray generator.
- The system allows the user to acquire, review, process, and store high resolution images, up to 43 cm x 35 cm (17 in x 13.8 in), at 2880 x 2400 pixel resolution and 14 bits depth.
- The ARiX RAD Acquisition Console™ provides digital images in compliance with the DICOM 3.0 standard.

Indications for Use: 21 CFR 807 92(a)(5)

The ARiX RAD Acquisition Console™ software, used together with a digital X-ray detector is a digital X-ray image processing system designed for acquiring images and processing acquired images. The main features of the software are controlling and interfacing the detector, acquiring images after X-ray, storing acquired images, managing data, optimizing window level and width of acquired images, rotating images, zooming images, measuring images and other features used for imaging processing. The ARiX RAD Acquisition Console™ system is compatible with the DICOM 3.x communications standard. It can transfer images processed in PACS and print images with a film printer compatible with DICOM 3.0 by using DICOM and network systems.

The ARiX RAD Acquisition Console™ system is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only and users must be qualified to create and diagnose radiological image data. The main functions of the ARiX RAD Acquisition Console™ system are as follows:

a) Acquisition and storage of digital X-ray images from a digital X-ray Detector.
b) Input Study information (patient information, exam information).
c) Management of stored (archived) images.
d) Image processing for enhancement of archived images.
e) Review of stored images.
f) Editing of images.
g) DICOM conformance (e.g. DICOM Storage, DICOM Work list, DICOM Print, etc.)
h) For a DR system (X-ray machine and generator and Digital X-ray detector, etc.) or a need to interface with installed X-ray system, the:
    - Ability to configure X-ray exposure condition (kVp, mA, Sec etc) for various body parts and positions.
    - Communication between Generator Console and ARiX RAD Acquisition Console™ system.

The X-ray generator control function depends on the X-ray Generator company. The X-ray generator is not part of the ARiX RAD Acquisition Console™ system since the ARiX RAD Acquisition Console™ system can only interface and control the Generator by the algorithm provided by the X-ray Company. The ARiX RAD Acquisition Console™ system can only select or change values of X-ray exposure parameters (kVp, mA second or kVp; mAs) according to the defined value determined by each X-ray company. The ARiX RAD Acquisition Console™ system does not control exposure and electrical change and calibration X-ray. If the X-ray

generator does not allow interfacing with external software (e.g. ARiX RAD Acquisition Console™ system), the ARiX RAD Acquisition Console ™ system software cannot be interfaced with X-ray Generator.

Technological Characteristics: 21 CFR 807 92(a)(6)

ARiX RAD Acquisition Console™ device is a software product that handles digital medical images. The device does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

Nonclinical Testing:

The complete system configuration has been assessed and tested at the factory and has passed all predetermined in-house testing criteria. The Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by the ARiX RAD Acquisition Console™ software in each operational mode and followed the process documented in the System Validation Test Plan. Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for ARiX RAD Acquisition Console™ contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The subject device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Therefore, ARiX RAD Acquisition Console™ is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 20, 2013

COMPAÑÍA MEXICANA DE RADIOLOGÍA CGR, SA de CV
C/O Carl Alletto
1600 Manchester Way
Corinth, Texas 76210

Re: K123650
Trade/Device Name: ARiX RAD Acquisition Console
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 1, 2012
Received: November 27, 2012

Dear Carl Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Janine Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123650

Device Name: ARiX RAD Acquisition Console™

Indications For Use:

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The ARiX RAD Acquisition Console™ system does not control exposure and electrical change and calibration X-ray. If the X-ray generator does not allow interfacing with external software (e.g. ARiX RAD Acquisition Console™ system), the ARiX RAD Acquisition Console ™ system software cannot be interfaced with X-ray Generator.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) 123650